

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A.,
INC.,

Plaintiff and
Counterclaim-Defendant,

V.

MYLAN PHARMACEUTICALS INC.,

Defendant and
Counterclaim-Plaintiff.

C.A. No. 19-2216-RGA

**DECLARATION OF PRESTON IMPERATORE IN SUPPORT OF
MYLAN PHARMACEUTICALS INC.'S REDACTIONS TO D.I. 384, 385, 387, 388, 390,
AND 391**

I, Preston Imperatore, hereby declare, under penalty of perjury pursuant to 28 U.S.C. § 1746, as follows:

1. I am employed by Mylan Inc. as Patent Litigation counsel. Defendant and Counterclaim Plaintiff Mylan Pharmaceuticals Inc. (“MPI”) is wholly owned by Mylan Inc., which is wholly owned by Viatris Inc. (collectively, “Mylan”).

2. As part of my duties, I supervise the redaction of Mylan's confidential information in the litigations that I manage for Mylan.

3. I submit this declaration based on my personal knowledge and in support of the proposed redacted filing of:

a. Takeda Pharmaceuticals U.S.A., Inc.’s (“Takeda”) Opening Brief in support of its Motion for Summary Judgment for No Damages (D.I. 384) and Exhibits 6, 7, and 8 to the Declaration of Porter F. Fleming, Esq. in Support of Takeda’s Motion for

Summary Judgment for No Damages, dated January 24, 2025 (D.I. 385)

(collectively, “Takeda’s Motion for Summary Judgment for No Damages”).

- b. Takeda’s Opening Brief in support of its Motion to Exclude the Opinions of Ivan Hofmann and James Leonard Under Fed. R. Evid. 702 (D.I. 387) and Exhibits 1, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, and 23 to the Declaration of Porter F. Fleming, Esq. in Support of Takeda’s Motion to Exclude the Opinions of Ivan Hofmann and James Leonard Under Fed. R. Evid. 702, dated January 24, 2025 (D.I. 388) (collectively, “Takeda’s Motion to Exclude”).
 - c. MPI’s Opening Brief in support of *Daubert* Motion to Exclude Expert Testimony of John O’Connor and Dr. Nisha Mody (D.I. 390) and Exhibits 2, 4, 5, and 6 to the Declaration of Sheryl Shapiro Bassin in Support of MPI’s *Daubert* Motion to Exclude Expert Testimony of John O’Connor and Dr. Nisha Mody, dated January 24, 2025 (D.I. 391) (collectively, “MPI’s Motion to Exclude”).
4. If asked to do so, I could and would testify competently to the matters contained herein.
 5. The proposed sealing redactions relate to MPI’s highly confidential information, disclosure of which “will work a clearly defined and serious injury” to MPI. *See In re Avandia Marketing*, 924 F.3d 662, 672 (3d Cir. 2019).
- I. Redactions to Takeda’s Motion for Summary Judgment for No Damages (D.I. 384 and D.I. 385)**
6. The proposed redactions to D.I. 384 are limited to the confidential terms of a stipulation entered into by MPI and Takeda on December 5, 2019 concerning MPI’s sale of its generic colchicine product that is the subject of this litigation. These terms reflect MPI’s highly confidential business considerations related to product sales, as well as confidential and sensitive

litigation strategy of the parties. Accordingly, the parties agreed that the terms of the stipulation would remain confidential. *See* D.I. 257 ¶ 6. These redactions are consistent with those previously submitted to and approved by this Court in connection with Takeda's Reply Brief In Further Support of its Motion for a Rule 54(b) Final Judgment as to Takeda's Claims and to Stay MPI's Counterclaims and MPI's Opposition to Takeda's Motion to Strike Portions of the Expert Report of Ivan Hofmann. *See* D.I. 257; D.I. 262; D.I. 356; D.I. 361.

7. The proposed redactions to Exhibit 6 (D.I. 385) are limited MPI's fees and costs incurred while litigating this action and descriptions of the discount provided by counsel to MPI in connection with same. *See* Ex. 6 (D.I. 385) at 5-6. This information would harm MPI because it would allow competitors insight into its litigation strategies. These redactions are consistent with those previously submitted to and approved by this Court in connection with the parties' letters to the Court dated September 30, 2024 and October 2, 2024. *See* D.I. 331; D.I. 334; D.I. 338; D.I. 340.

8. The proposed redactions to Exhibit 7 (D.I. 385) are limited to MPI's fees and costs incurred while litigating this action. This information would harm MPI because it would allow competitors insight into its litigation strategies. *See* Ex. 7 (D.I. 385) at 4-5, 7. These redactions are consistent with those described in paragraph 6, above, and the relevant prior filings described therein.

9. The proposed redactions to Exhibit 8 (D.I. 385) are limited to MPI's fees and costs incurred while litigating this action and descriptions of the discount provided by counsel to MPI in connection with same. This information would harm MPI because it would allow competitors insight into its litigation strategies. *See* Ex. 8 (D.I. 385). These redactions are

consistent with those described in paragraph 6, above, and the relevant prior filings described therein.

II. Redactions to Takeda's Motion to Exclude (D.I. 387 and D.I. 388)

10. The proposed redactions to D.I. 387 are limited to references to MPI's customers, inventory of its colchicine product, prices offered and agreed to between MPI and its customers, and customer agreements. This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales and manufacturing strategies. These redactions are consistent with those previously submitted to and accepted by this Court in connection with MPI's Brief in Opposition to Takeda's Motion to Strike Portions of the Expert Report of Mr. Ivan Hofmann and the concurrently-filed Declaration from Sheryl Shapiro Bassin, dated November 21, 2024. *See* D.I. 355; D.I. 356; D.I. 361; D.I. 362.

11. The proposed redactions to Exhibit 1 (D.I. 388) are limited to MPI's outside counsel's rates, MPI's fees and costs incurred while litigating this action, and descriptions of the discount provided by counsel to MPI in connection with same. *See* Ex. 1 (D.I. 388) at 5-6. This information would harm MPI because it would allow competitors insight into its litigation strategies. These redactions are consistent with those described in paragraph 6, above, and the relevant prior filings described therein.

12. Exhibit 7 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redaction to Exhibit 7 is limited to references to MPI's customers and contract prices for its colchicine product. *See* Ex. 7 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales strategies. These redactions are

consistent with those previously submitted to and approved by this Court in connection with the Declaration of Porter F. Fleming, Esq. in Support of Takeda's Motion to Strike Portions of the Expert Report of Mr. Ivan Hofmann, dated November 7, 2024. *See* D.I. 349 at Ex. 1; D.I. 353 at Ex. 1.

13. Exhibit 8 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 8 are limited to references to MPI's customers, communications with MPI's customers, and MPI's offered pricing and related analysis. *See* Ex. 8 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales strategies. These redactions are consistent with those previously submitted to and approved by this Court in connection with the Declaration of Porter F. Fleming, Esq. in Support of Takeda's Motion to Strike Portions of the Expert Report of Mr. Ivan Hofmann. *See* D.I. 349 at Ex. 1; D.I. 353 at Ex. 1.

14. Exhibit 9 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 9 are limited to references to MPI's customers and communications with MPI's customers regarding the potential sale of MPI's generic colchicine product. *See* Ex. 9 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales strategies. These redactions are consistent with paragraph 13, above, and the relevant prior filings described therein.

15. Exhibit 10 (D.I. 388) is an internal document produced by MPI in this action which was designated “Outside Counsel Only” by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 9 are limited to references to MPI’s customers and communications with MPI’s customers regarding the potential sale of MPI’s generic colchicine product. *See* Ex. 10 (D.I. 388). This information reflects MPI’s highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI’s sales strategies. These redactions are consistent with paragraph 13, above, and the relevant prior filings described therein.

16. The proposed redactions to Exhibit 11 (D.I. 388) are limited to references to MPI’s prices, customer agreements, negotiations with customers, launch strategy, and the calculation of net price. *See* Ex. 11 (D.I. 388). This information reflects MPI’s highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI’s customer negotiation strategies and launch and pricing strategies. These redactions are consistent with those previously submitted to and approved by this Court in connection with MPI’s Brief in Opposition to Takeda’s Motion to Strike Portions of the Expert Report of Mr. Ivan Hofmann and the concurrently-filed Declaration of Sheryl Shapiro Bassin, dated November 21, 2024. *See* D.I. 355; D.I. 356; D.I. 361; D.I. 362.

17. Exhibit 12 (D.I. 388) is an internal document produced by MPI in this action which was designated “Outside Counsel Only” by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 12 are limited to references to MPI’s customers and communications with MPI’s customers regarding the potential sale of MPI’s generic colchicine product. *See* Ex. 12 (D.I. 388). This information reflects MPI’s highly sensitive business

information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales strategies.

18. Exhibit 13 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 13 are limited to references to MPI's customers and communications with MPI's customers regarding the potential sale of MPI's generic colchicine product. *See* Ex. 13 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales strategies.

19. Exhibit 14 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 14 are limited to the identity of MPI's customers, customer agreements, manufacturing data, and pricing and sales data reflecting MPI's negotiation strategies. *See* Ex. 14 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales and manufacturing strategies.

20. Exhibit 15 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 15 are limited to references to the identity of MPI's customers, customer agreements, and inventory, pricing, and market data. *See* Ex. 15 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales and manufacturing strategies.

21. Exhibit 16 (D.I. 388) is an internal document produced by MPI in this action which was designated “Outside Counsel Only” by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 16 are limited to the references to the identity of MPI’s customers and prices offered and agreed to between MPI and its customers. *See* Ex. 16 (D.I. 388). This information reflects MPI’s highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI’s sales strategies. These redactions are consistent with those previously submitted to and approved by this Court in connection with the Declaration of Porter F. Fleming, Esq. in Support of Takeda’s Motion to Strike Portions of the Expert Report of Mr. Ivan Hofmann. *See* D.I. 349 at Ex. 1; D.I. 353 at Ex. 1.

22. Exhibit 17 (D.I. 388) is an internal document produced by MPI in this action which was designated “Outside Counsel Only” by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 17 are limited to the references to the identity of MPI’s customers and prices offered and agreed to between MPI and its customers. *See* Ex. 17 (D.I. 388). This information reflects MPI’s highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI’s sales strategies. These redactions are consistent with those described in paragraph 21, above, and the relevant prior filings described therein.

23. Exhibit 18 (D.I. 388) is an internal document produced by MPI in this action which was designated “Outside Counsel Only” by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 18 are limited to the references to the identity of MPI’s customers and prices offered and agreed to between MPI and its customers. *See* Ex. 18 (D.I. 388). This information reflects MPI’s highly sensitive business information related to its

colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales strategies. These redactions are consistent with those described in paragraph 21, above, and the relevant prior filings described therein.

24. Exhibit 19 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 19 are limited to the references to the identity of MPI's customers and prices offered and agreed to between MPI and its customers. *See* Ex. 19 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales strategies. These redactions are consistent with those described in paragraph 21, above, and the relevant prior filings described therein.

25. Exhibit 20 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 20 are limited to MPI's confidential manufacturing data. *See* Ex. 20 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's manufacturing strategies.

26. Exhibit 21 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 21 are limited to MPI's confidential manufacturing data. *See* Ex. 21 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's manufacturing strategies.

27. The proposed redactions to Exhibit 22 (D.I. 388) are limited to testimony regarding MPI's launch strategy, inventory, and manufacturing data. *See* Ex. 22 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's launch and manufacturing strategies. These redactions are consistent with those previously submitted to and approved by this Court in connection with MPI's Brief in Opposition to Takeda's Motion to Strike Portions of the Expert Report of Mr. Ivan Hofmann and the concurrently-filed Declaration from Sheryl Shapiro Bassin, dated November 21, 2024. *See* D.I. 355; D.I. 356; D.I. 361; D.I. 362.

28. Exhibit 23 (D.I. 388) is an internal document produced by MPI in this action which was designated "Outside Counsel Only" by MPI under the Protective Order (D.I. 183). The proposed redactions to Exhibit 23 are limited MPI's confidential manufacturing data. *See* Ex. 23 (D.I. 388). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's manufacturing strategies.

III. Redactions to MPI's Motion to Exclude (D.I. 390 and D.I. 391)

29. The proposed redactions to D.I. 390 are limited to MPI's manufacturing capabilities and supply chain for colchicine in late 2019 and the rates of outside counsel for MPI and Takeda. This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's manufacturing capabilities and the litigation strategies of the parties.

30. The proposed redactions to pages 7, 10, 14, and 15 of Exhibit 2 (D.I. 391) are limited to MPI's fees and costs incurred while litigating this action and a description of the

discount provided by counsel to MPI in connection with same. *See* Ex. 2 (D.I. 391) at 7, 10, 14-15. This information would harm MPI because it would allow competitors insight into its litigation strategies. These redactions are consistent with those described in paragraph 7, above, and the relevant prior filings described therein.

31. The proposed redactions to Exhibit 4 are limited to references to the identity of MPI's customers, customer agreements, manufacturing data, pricing and sales data, and MPI's damages as calculated by its retained expert. *See* Ex. 4 (D.I. 391). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales and manufacturing strategies. These redactions are consistent with those previously submitted to and approved by this Court in connection with the Declaration of Porter F. Fleming, Esq. in Support of Takeda's Motion to Strike Portions of the Expert Report of Mr. Ivan Hofmann. *See* D.I. 349 at Ex. 1; D.I. 353 at Ex. 1.

32. The proposed redactions to Exhibit 5 (D.I. 391) are limited to references to the identity of MPI's customers, customer agreements, manufacturing data, pricing and sales data, and MPI's damages as calculated by its retained expert. *See* Ex. 5 (D.I. 391). This information reflects MPI's highly sensitive business information related to its colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's sales and manufacturing strategies. These redactions are consistent with those described in paragraph 31, above, and the relevant prior filings described therein

33. The proposed redactions to pages 294-297 of Exhibit 6 (D.I. 391) are limited to references to the identity of MPI's customers and manufacturing data. *See* Ex. 6 (D.I. 391) at 294-297. This information reflects MPI's highly sensitive business information related to its

colchicine product, the disclosure of which would harm MPI because it would allow competitors insight into MPI's manufacturing strategies.

34. Redaction of the information in D.I. 384, 385, 387, 388, 390, and 391 is appropriate as the information represents highly sensitive business information, and the disclosure of such information will cause MPI a clearly defined and serious injury, including by disclosing competitive information that MPI's competitors would use to compete with MPI.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed on the 31st day of January, 2025 in Wexford, Pennsylvania.

/s/ Preston Imperatore
Preston Imperatore, Esq.